April 4, 2001

Dr. Harold Varmus
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Dear Dr. Varmus:

It was good to see a paper in SCIENCE that addressed an issue of great importance, authored by an individual whose bona fides for the task are totally beyond dispute. Should your clarion call be effective, the U.S. scientific community will be in your debt to a far greater extent than it already is for the years you labored in it's behalf as Director, N.I.H.

A successful solution to the problem described in the SCIENCE paper will not be easily achieved, however. In the short term, continuation of current practice is a win-win for the whole cabal of stakeholders in the rapacious game of gaining an entitlement on funds for a particular discipline/ field/ speciality (D/F/S)

- potential grantees acquire access to a dedicated bloc of funds, insuring the opportunity for more scientists in the field to receive awards. Both these individuals as well as their non-research colleagues get a boost in status by virtue of the national recognition of their domain of knowledge and expertise. "If the Eye is worthy of National Institute status, why not the Ear?" Leaders in the push for recognition of the importance of a discrete D/F/S by according it National Institute status certainly win the respect and acclaim of their colleagues and advance their personal power and authority within their peer group.

  Parenthetically, it should be noted that, as long as the NIH uses decile ranking by initial review groups (IRGs) to set pay lines, it is not even necessary to secure full institute status in order to obtain a dedicated "pot" of money; the objective can be accomplished by the simple expedient of persuading the NIH to create a Study Section or equivalent under the plea that, to ensure review of applications in that field be evaluated by people more knowledgeable about it and to likewise ensure that these applications not be summarily dismissed when assigned to an IRG of broader scope. The Physical Medicine and Rehabilitation

(PM&R)people presented their argument for a PM&R Study Section circa 1990; Larry Earley from the U. of PA. rebutted it on behalf of the AAMC.

- dedicated and zealous lay volunteers and voluntary societies, many animated by the personal tragedy of having lost a loved one to some disease --- rare or common --- for which research support is, in their view, insufficient win a major victory by seeing their efforts pay off in an increase in appropriations for their area of concern; but they really hit the "jack pot", if they succeed in highlighting the visibility of their "cause" in the organizational structure of the NIH.

- members of Congress love being magnanimous to their friends --- and thereby enhancing their local and national reputations --- especially when the cost to them is apparently trivial.

- former departmental (DHEW and DHHS) employees (OS, OASH, NIH), usually after a stint of service on the Hill, whether directly employed or seconded there by the Department, have made handsome livings for many years by shepherding the advocates for new Institutes through the arcana of bureaucratic processes and procedures.

- members of the National Advisory Councils of existing Institutes have, I suspect, used their positions to encourage proliferation. A careful reading of the saga of the evolution of the original NIAMD --- with the sequential establishment within it of: convoluted structures of: National Commissions (to plan a comprehensive program for a subfield of the Institute), of Interagency Coordinating Committees, of National Advisory Boards and soon, VOILA!, a new member of the NIH family of Institutes --- convinced me that the process was driven by members of the NIAMD Council and it's lineal descendants.

- NIH, officially, including some BID Directors, have either endorsed or weakly opposed fragmentation, since it has historically increased funding for the new field, at small cost to existing programs.

- Departmental officials, even when urged by the NIH, have been reluctant to tangle with the Congress on this issue in other than perfunctory and stereotyped language. I have long suspected that the OS views it as a useful bargaining chip in negotiations with the Legislature. Ditto the OMB and, in the rare event that the problem ever surfaces at that level, the Office of POTUS.

This array of "profiteers", each with at least something to gain, and many with prospects of huge rewards, will be resistant to a "cease and desist" policy, premised on the catastrophic long range impact sketched in your SCIENCE paper. Whenever the question arises about "who will take care of the Commons?", the users and exploiters of that Commons simply continue as usual until the resource is an usable shambles. Is there some carrot that can be offered to the advocates for a new Institute that will be perceived by them as an equally satisfying alternative?

Speaking both as an insider --- I was the Executive Director of what was then called the Assembly of the Life Sciences of the NRC from 1974 to 1976 --- and as a longtime spectator of NAS / NRC

/ IOM efforts, I think your confidence that a REPORT from any of these entities --- or from any government agency --- will have an impact on the problem is misplaced. In 1983, at the request of the NIH, the IOM constituted a Committee of distinguished scientists and health policy experts, chaired by Jim Ebert, to examine the problem of Institute proliferation that had been aired in Congressional hearings during the prior year. I was the staff person assigned by the AAMC to manage AAMC interactions with, and responses to, the Ebert Committee activities.

Our written submission **(ATTACHMENT A)** stated the problem as the AAMC saw it --- astonishingly unchanged, except in degree for two decades --- and offered a couple of solutions, designed to give the more obscure D / F / S a more prominent place in the sun --- our "carrot". Surprisingly large amounts of the content of our submission ended up in the final report of the IOM Committee; whether the ideas that we presented were uniquely attractive or were simply widely held and generally accepted beliefs, included in many submissions, I have no way of knowing. But the IOM Report did make a strong case against proliferation.

Bob Berne's oral testimony **(ATTACHMENT B)** for the AAMC focused mainly on trying to convince the Committee to persuade the Congress to focus it's efforts on policy oversight and to leave decisions of a predominantly scientific character to the science agencies, advised by the scientific community. There is no evidence that this thesis moved the IOM Committee in the least.

As was it's wont in dealing with important Washington-generated Reports, the AAMC established a Committee, headed by Bob Berliner, to critique the IOM effort The ensuing AAMC Report **(ATTACHMENT C)** was sent to the Deans of all U.S. medical schools, to the Officers and to two representatives to the AAMC of each of about 90 Academic Societies and to several officials in each of the AAMC-affiliated teaching hospitals. Thus, the academic medical community knew, or should have known, about the IOM's position on new Institute proliferation and the generally enthusiastic endorsement of that position by the AAMC.

You may recall that another distinguished committee, the Presidents Biomedical Research Panel, chaired by Franklin Murphy, a former medical school Dean and, during the life of the Panel, publisher of the Los Angeles Times, did a very comprehensive review of the NIH and reported the results to the president in 1976. I recently gave my multivolume copy which took up more space on my bookshelves than could spare to the NIH Historian, Victoria Harden, or to the AAMC Archivist, or to someone of comparable ilk, hoping that they would treasure rather than trash it, the fate of so many Reports. The Presidents Panel, inter alia, strongly recommended against further Institute proliferation.

And what were the results of these thoughtful attempts to deal with a practice whose long-term implications are the paralysis of the NIH, as the Lilliputians immobilized Gulliver, with appropriated funds frozen into discrete, dedicated, and walled-off compartments and with no ability to spend them flexibly or fungibly or to transfer them across the barriers. I'd have to say that the results were nil; that these Reports failed utterly to stop, yeah, even to slow this baleful practice. And thus I'd have to predict that another use of a twice failed recipe is an exercise in futility. One reason these Reports are ignored, in my humble opinion, is that there is no follow-through by the Committees that wrote them but simply a cover transmittal letter to a Departmental Secretary or a Congressional Committee Chair.

The package will usually be opened by a clerk and referred to a junior staff person who often lacks enough context or institutional memory to appreciate the significance of the problem described or the solutions proposed or who might decide that the issue had been eclipsed by time. The Principal that initiated the request for the Report may never see it or hear of it.

What's really needed is a new strategy, planned from a zero base by people of your ilk who understand the problem and are willing to put the long-term health of the NIH --- that is, of the nation's health --- above their own short-term, parochial and territorial interests. The Planning group should make a long-term commitment to serve as Vigilantes and to take preventive action whenever the rumor surfaces that another revisionist raid on the organizational structure of the NIH is getting started.

One strategy might be to get legislation passed to limit proliferation. However, it must be recognized that new legislation has to be initiated by the legislative Committees of the Congress that are continuously struggling to maintain control of the executive agencies under their jurisdiction. This has been a perennial problem for NIH's Legislative Committees that appear to many observers to have lost control of the agency to NIH's Appropriations Committees whose understanding and sympathy for the agency have been so evident for so long. The House (then, Interstate and Foreign, now) Energy and Commerce Committee seems to me to have been particularly active in this respect, e.g., trying over several years in the late 1970's to place time and appropriation ceilings on all Institutes and playing a large role in the dismemberment and reassembly of the NIAMD. It would be a tough sell to persuade this legislative committee to enact a prohibition on new National Institutes. The contest for control of the NIH between it's Legislative and it's Appropriations Committees has been a reality, at some times more lively than at others, since the retirement of Sen. Lister Hill, who chaired *both* Committees. Hill apparently believed he could do everything he wanted done through the appropriations process and didn't want the House to complicate life for him by mucking with statutory authorities. He therefore just "sat on" proposals from the House Legislative Committee until the latter resigned itself to an inactive role.

But this is not the time nor place to strategize, nor should I engage in the exercise. What's needed is a small but wise group of scientists and research policy "wonks", and not anyone so long "out of the loop" as myself, to try to come up with a better way to handle this recurrent and portentous issue. Lots of luck.

Sincerely

Thomas L. Hwang MD